

In re Appln. of Adin et al.  
Attorney Docket No. 229420

*CLAIM AMENDMENTS*

1. (Original) A stable and easy to formulate amorphous solid, suitable for the preparation of solid pharmaceutical compositions comprising a mixture of an amorphous active pharmaceutical ingredient and at least one pharmaceutically acceptable inactive ingredient.
2. (Original) The stable solid mixture of claim 1, wherein the active pharmaceutical ingredient is selected from the group consisting of donepezil hydrochloride and losartan potassium.
3. (Original) The stable solid mixture of claim 1, wherein the inactive ingredient is selected from the group consisting of lactose, polyvinylpyrrolidone and polyethylene glycol and mixtures thereof.
4. (Original) The stable solid mixture of claim 1, wherein the ratio of inactive to active components of said mixture is in the range of about 10/1 to about 0.3/1.
5. (Original) The stable solid mixture of claim 1, wherein the ratio of inactive to active components of said mixture is in the range of about 3/1 to about 1/1.
6. (Original) The stable solid mixture of claim 1, wherein the ratio of inactive to active components of said mixture is in the range of about 3/1.
7. (Original) The stable solid mixture of claim 1, wherein the ratio of inactive to active components of said mixture is in the range of about 1/1.
8. (Original) The stable solid mixture of claim 1 wherein the active ingredient is donepezil hydrochloride, the inactive ingredient is lactose and the lactose/donepezil hydrochloride ratio is 3/1.
9. (Original) The stable solid mixture of claim 1 made by lyophilization.

10. (Original) A process for the preparation of the stable solid mixture of claim 9 comprising the following steps:

- a) preparing a solution of the active pharmaceutical ingredient and the inactive ingredient in a suitable solvent;
- b) freezing the solution by cooling;
- c) freeze-drying the frozen product of step b;
- d) drying the freeze-dried product of step c; and
- e) optionally grinding or milling the product of step d.

11. (Original) A process, according to claim 10, wherein the solvent is water.

12. (Currently Amended) A process, according to claim 10, wherein the freeze-drying is carried out at a temperature range of about -60°C to +10°C.

13. (Original) A process according to claim 10, wherein the drying of step d is carried out at a temperature range of about -10°C to about +40°C.

14. (Original) A solid pharmaceutical composition comprising a stable solid amorphous mixture as claimed in claim 1 in combination with a pharmaceutically acceptable carrier.

15. (Currently Amended) A solid pharmaceutical composition ~~as claimed in claim 14, whenever~~ comprising the mixture prepared according to claim 10 in combination with a pharmaceutically acceptable carrier.

16. (Original) A process as claimed in claim 10 wherein the amorphous solid mixture obtained is chemically stable.

17. (Original) A process according to claim 10 wherein the amorphous solid mixture obtained is physically stable.

18. (Original) A process as claimed in claim 10 wherein the amorphous solid mixture obtained remains physically stable after heating, compressing, milling and combinations thereof.